EXPERT REPORT OF KEVIN G. MCANANEY

I. Introduction

I have been asked to provide expert testimony in the case of United States ex rel. Saldivar v. Fresenius Medical Care, Case No. 1:10-CV-01614-AT, now pending in the United States District Court for the Northern District of Georgia. I am thoroughly familiar with the federal health care fraud and abuse laws and served as the Chief, Industry Guidance Branch, Office of Counsel to the Inspector General of the U.S. Department of Health and Human Services from January 1997 until May 2003. I have been asked for my opinions as to whether it was reasonable in the time period from approximately 2003 to 2010 for Fresenius to believe that it could bill Medicare for overfill of Epogen and Zemplar that it administered to Medicare enrollees. For the reasons discussed below, Fresenius' understanding was consistent with the consensus view among experienced health care counsel, industry participants, and regulators at the time.

II. Background and Qualifications

1. I specialize in federal health care fraud and abuse laws and have over 35 years of experience in health law, including substantial experience working in the federal government on the regulatory framework upon which I am opining. My practice for the past 17 years has focused virtually exclusively on the application of the federal health care anti-kickback statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and the physician self-referral law ("Stark law"), 42 U.S.C. § 1395nn, to healthcare transactions, including as a predicate for the civil False Claims Act.

2. I was the Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General of the United States Department of Health and Human Services ("HHS") from 1997 until 2003. Unlike other components of HHS, the Office of Inspector General ("OIG") does not operate any government programs. The Office of the Inspector General is tasked with investigating fraud, waste, and abuse in the federal programs administered by HHS, including the Medicare and Medicaid programs. It also represents the interests of HHS and the Centers for Medicare and Medicaid Services ("CMS") in connection with false claims act litigation prosecuted by the United States Justice Department. OIG is independent and separate from CMS.

3. Pursuant to the Medicare and Medicaid Patient and Program Protection Act of 1987 and the Health Insurance Portability and Accountability Act of 1996, Congress authorized the Secretary of HHS to issue regulations and guidance with respect to the AKS. The Secretary of HHS has delegated that authority to the Inspector General, who in turn has delegated his authority to the Office of Counsel to the Inspector General.

4. As Chief of the Industry Guidance Branch of the Office of Counsel, I was responsible for developing regulations and formal guidance to the regulated community through advisory opinions, fraud alerts and special bulletins, compliance program guidance, and regulations related to the fraud and abuse statutes and regulations enforced by the OIG, including the AKS and the Stark law. In performing those duties, I regularly consulted with officials at CMS with respect to reimbursement policies and guidance.

5. I also was a principal author of the 1999 AKS "safe harbor" rulemaking, 64 Fed. Reg. 63518 (November 19, 1999), which revised the discount safe harbor. I was the principal author of several advisory opinions, compliance program guidance, and informal "guidance" letters issued by the OIG during my tenure related to the issue of discounts and free goods. I also was the principal author of the Stark Phase I and Phase II rulemakings, 66 Fed. Reg. 856 (January 4, 2001); 69 Fed. Reg. 16054 (March 26, 2004). In addition, I worked closely with the United States Department of Justice ("DOJ") in developing cases involving the AKS and Stark law, including the use of such claims as predicates for False Claims Act litigation. I was also hired as a contractor by CMS to provide the first draft of the Phase III rulemaking, 72 Fed. Reg. 51012 (Sept. 5, 2007).

6. My duties at OIG included regularly providing informal oral guidance in response to inquiries from the public and other government agencies regarding the application of the AKS to various arrangements, including the propriety of billing Medicare for overfill and the propriety of billing Medicare for free goods.

7. Since May 2003, I have concentrated my practice on the regulation of Medicare fraud and abuse. I regularly counsel health care entities on the Stark law and AKS and regulations, the Civil Monetary Penalties Law, and the interplay of those statutes with the False Claims Act, including how to structure arrangements to comply with those laws. Clients have included CMS, the Office of the Assistant Secretary for Planning and Development in HHS, and the Medicare Payment Advisory Commission, an independent Congressional agency. I have regularly counseled clients on compliance issues related to discounts and the discount statutory and regulatory exceptions.

8. Prior to joining the OIG, I practiced health and regulatory law in the Dewey Ballantine law firm for 13 years, including 10 years as a partner. During that time I counseled clients on compliance with the federal health-care laws, including the federal anti-kickback statute and its statutory and regulatory discount exception.

9. I served from 1981 to 1983 as Assistant Counsel to New York Governor Hugh Carey with principal responsibility for legislation and litigation affecting the health and human services agencies, including the Medicaid program, and from 1980 to 1981 as the Director of Legal Affairs for the New York Hospital.

10. I graduated from the University of North Carolina at Chapel Hill in 1971 and from the Columbia University Law School in 1977.

11. I am a member of the Advisory Board for the Bureau of National Affairs' Health Care Fraud Reporter and a frequent speaker on health care fraud issues,

including numerous presentations relating to various discounting practices, the False Claims Act, and the federal anti-kickback statute. I was an adjunct professor at the University of Maryland Law School from 2002 to 2013. I am a past member of the Board of Directors of the American Health Lawyers Association. I have been a member of the Program Committee for the American Health Lawyers Association/Health Care Compliance Association's Health Care Fraud and Compliance Forum for the past six years and co-chair of the program committee for the past two years. A copy of my current curriculum vitae is attached as Exhibit 1 to this report.

12. My past testimonial experience is listed in the attached Exhibit 2. I have two publications within the last 10 years.[1] I based my opinions on my extensive experience and the matters described below. I have reviewed the materials cited herein and in Exhibit 4, as well as the materials in the attached Exhibit 3. I am being compensated at the rate of $500 per hour.

III. Summary of Opinions

13. Fresenius' understanding that it had purchased the Epogen ("EPO") and Zemplar overfill and was entitled to bill Medicare Part B for overfill administered to enrollees was reasonable and consistent with the opinions of experienced healthcare counsel, industry participants and regulators.

14. Fresenius' understanding that there is no general prohibition on billing Medicare for items received for "free" and that there was no prohibition on billing for overfill – prior to the promulgation of regulations in 2010 that were prospectively applied starting in 2011 for end-stage renal disease ("ESRD") facilities that did not opt in to the bundled payment program – was reasonable and consistent with the opinion of experienced healthcare counsel, industry participants, and regulators.

15. It was reasonable for Fresenius to believe it was appropriate to bill Medicare for overfill.

16. It would not have been reasonable for Fresenius to administer overfill without billing for it, as the provision of Epogen or Zemplar overfill to Medicare enrollees without charge to them or Medicare would be understood to potentially violate the Civil Money Penalty Law, 42 U.S.C. § 1320a-7a(a)(5), prohibiting the offer or transfer of remuneration to Medicare or Medicaid enrollees that is likely to influence their choice of providers or suppliers. For this same reason, regulators who understood that Fresenius was administering overfill would have understood that Fresenius was also billing for that overfill.

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[1] "Permissibility of Pharmaceutical Copayment Coupon Programs Under ACA," BNA's Health Care Fraud Report, August 21, 2013; "Discounts, Bundling, and Swapping: What Do the Fraud and Abuse Laws Really Prohibit?" (presented at various conferences, including conferences sponsored by the American Bar Association and the American Health Lawyers Association).

IV. Statement of and Bases for Opinion No. 1

17. Fresenius' belief that the overfill in vials of EPO and Zemplar was not "free" product was reasonable and consistent with the common understanding in the health care industry and among federal health care regulators. The common understanding shared by regulators and the regulated community alike was that all products, items, and services that were included in a transaction were "paid" for by the purchaser. The focus of regulatory concern in such transactions was not whether any of the goods were "free," but rather how the purchase price would be allocated among the various products so that the government would be able to understand approximately how much each item cost.

18. I understand that overfill is required to be supplied by manufacturers under FDA regulations. I further understand that the same amount of overfill is included in the vials provided to each purchaser. A purchaser cannot be given more (or less) overfill based on the quantity of drug purchased and the purchaser cannot acquire vials of drug that do not include overfill. Purchasers bought everything in the vial. Under these circumstances, it was reasonable for Fresenius to believe that overfill was included in the purchase price and that it was appropriate to use and bill overfill.

19. As part of my work in this case, I have reviewed David Kembel's September 25, 2012 deposition and exhibits, including exhibits 5 and 25 and in particular pages 113-114. Those exhibits set forth reasonable interpretations of the governing rules regarding the AKS and the discount safe harbor.

20. In any event, even if overfill is considered a discount on the purchase price, federal health care regulators at the U.S. Department of Health and Human Services shared the understanding that overfill would not be considered "free and not billable" since at least 1989. In OIG's initial proposed rulemaking creating certain "safe harbor" regulatory exceptions from the AKS, it expressly stated that extra goods or products of the same kind constituted a "discount" to be apportioned over all goods purchased, including the free goods.

> This proposed discount exemption closely follows the statutory language, limiting its application to reductions in the amount a seller charges in a specific transaction for a good or service to a buyer. … *This discount may take the form of a direct and explicit reduction in price, or of an indirect reduction that results from the offer of an extra quantity of the item purchased "at no extra charge."* This exemption specifically does not apply to remuneration in the form of other things of value, such as rebates of cash, other free goods or services, redeemable coupons, or credit towards the future purchases of other goods or services. 54 Fed. Reg. 3088, 3092 (January 23, 1989).

21. While the regulations were issued by the OIG, they were also reviewed and approved by the Health Care Financing Administration, the predecessor agency to

CMS and the DOJ. The regulations were signed by the Secretary of the U.S. Department of Health and Human Services, of which OIG and CMS were and are components.

22. The government has never deviated from its original guidance that the purchase price must be allocated over all goods and services received as part of a transaction. In 1997, the OIG audited freestanding and hospital based dialysis facilities as part of a review of Epogen reimbursement. One of the key findings of the report was that a number of facilities were extracting overfill and using it in patient care. Significantly, consistent with the common understanding, OIG concluded that the utilization of overfill "would materially affect each provider's *cost*." OIG Report: Review of Epogen Reimbursement, pgs. 1, 8 (A-01-97-00509)(November 1997). In other words, the OIG expected that the purchase price paid by the facilities for Epogen had to be allocated over the entire amount of product actually received.

23. That understanding was consistent with my understanding while I was Chief of the Industry Guidance Branch at OIG. As part of my regular duties, I responded to inquiries from the public regarding billing for extra product, including overfill. Consistent with what I understood the government's position to be, I routinely explained that health care entities could bill Medicare for overfill and other additional product included in a single transaction. I was aware of no basis for concluding that overfill was not included in the purchase price. My view was unremarkable and consistent with the general understanding in the regulated community and among federal regulators.

24. In the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers, issued in 2003, the OIG again stated that extra product, even if characterized as "free," was considered part of the transaction and had to be allocated a portion of the purchase price.

> Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. *Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products…*

68 Fed. Reg. at 23733-23734 (emphasis added.)

25. The changes to the average wholesale price methodology and the switch to the average sales price ("ASP") methodology beginning January 1, 2005 (or January 1, 2006, in the case of dialysis facilities) were not understood by regulators, experienced health care counsel, or the industry as changing the status of drug overfill from purchased product to a free good. The new payment methodologies were understood to set a more realistic cap on Medicare's payment for these drugs,

based on readily accessible information about the sales price and a fixed 6% add-on to provide some profit. As Mr. Hartstein acknowledged in his testimony on behalf of CMS, the ASP methodology is not one that "relies on Medicare principles of reasonable cost." Hartstein Depo., p. 103.

26. I am aware of nothing that would indicate that CMS or the health care industry understood that the ASP methodology changed in any way the reimbursability of overfill by federal health care programs. In my experience, when CMS makes a significant change in reimbursement policy, such as disallowing coverage for a product previously covered, it makes the change very publically and unambiguously. If the adoption of the ASP methodology was understood to make overfill, previously reimbursable, now unreimbursable, CMS would have made some public announcement, especially since it would require purchasers to waste valuable product. For example, CMS issued explicit guidance prohibiting reimbursement for certain free goods, including drug samples, items billed "incident to" physician services (which does not apply to ESRD companies), and goods provided as part of a clinical trial. When the product is billed to the patient (as Fresenius was instructed and required to do with regard to all administered units of Epogen and Zemplar), the product is not free to the beneficiary and not included in rules prohibiting such billing to Medicare. In the absence of such explicit guidance, the industry understood there was no change in prior policies.

27. The longstanding government position that all goods in a given transaction were paid for in the purchase price, regardless of their characterization as "free" or "no charge," was unquestioned by the health care industry because it was consistent with common sense. Regulators and those in the industry understood (and it was certainly reasonable for any person to so believe) that in the case of overfill, the purchaser bought everything in the vial. The critical concern for health care purchasers in the event the government took the position that the arrangement was a discount was to insure that the transaction, including overfill, would qualify for the discount statutory exception or regulatory safe harbor.

28. CMS itself has acknowledged that it never stated that overfill was excess free product or alerted companies that when they purchased a vial they were purchasing just the amount of drug defined on the packaging or label. Hartstein Depo., p. 75. There was no statement that would have alerted a company that CMS viewed overfill as being provided without charge. Id.

29. I was and am aware that Fresenius was using and billing for overfill and have reviewed Fresenius' discussions of overfill with the various government agencies that review its conduct (OIG, CMS, and DOJ). Fresenius' actions were consistent with the industry understanding that overfill could be billed to Medicare as part of what was acquired with the purchase and that if overfill was considered a discount, it would fall within the discount safe harbor. Fresenius' contracts with Amgen expressly stated that it was purchasing "vials." The contracts with Abbot stated that it was purchasing a "vial" of Zemplar. Fresenius accurately disclosed its costs on its cost reports either in the same fiscal year or the following year. Moreover, as to Epogen, Fresenius even disclosed the number of units administered, including

overfill, which allowed regulators including OIG to calculate the actual per-unit cost of Epogen, including overfill. Fresenius complied with the discount safe harbor and thus it reasonably viewed its overfill practices to be legal.

30. In addition to complying with the discount regulatory safe harbor, Fresenius took steps to insure that the government was fully aware of its use of overfill and its effect on its costs for Epogen and Zemplar. While these actions were not required to qualify for the discount safe harbor, they were intended to insure full transparency with respect to Fresenius' Epogen and Zemplar purchases. These disclosures and related documents reflecting the government's awareness of Fresenius' overfill practices are listed in Exhibit 4, attached hereto. Likewise, other industry participants made equally clear disclosures. See Ex. 4. Experienced counsel regularly recommended such disclosures as an extra precaution to ensure a transaction was transparent to the government. Given its history of disclosures, it was reasonable for Fresenius to believe that if the government had an issue with its practices, the government would have alerted Fresenius of this fact.

31. From the materials that I have reviewed, Fresenius always made clear to the federal authorities that it was using the overfill, which was reducing Fresenius's costs for Epogen and Zemplar. I know that while I was at OIG, persons at CMS and OIG understood that Fresenius and other ESRD suppliers were using and billing for overfill and such persons believed the practice was lawful. Fresenius' disclosure of its use of overfill is consistent with the common understanding that overfill was included in the product Fresenius purchased.

32. From the time I left OIG in 2003 until the promulgation of the overfill regulation in 2010, it continued to be the understanding of experienced health care counsel, industry participants, and regulators that drug overfill was included in the goods purchased by a buyer. In other words it was product that was purchased and not "free."

V. Statement of and Bases for Opinion No. 2

33. It was reasonable and consistent with the opinion of experienced health care counsel, health care entities, and regulators for Fresenius to believe that there is no general prohibition on Part B suppliers, including freestanding ESRD suppliers, billing Medicare Part B for items received for "free" or for which the suppliers did not incur costs. Before, during, and after my service with OIG, I always understood that Part B suppliers could bill for items and services, regardless of whether they had been purchased or received for free, unless there was an express exclusion from coverage. That understanding was widely shared in the health care industry.

34. First, from its inception, Medicare Part B reimbursement was based on the physician or supplier's charges to the enrollee for the services and not on the cost of providing the services. The Medicare Part A Hospital program and the Medicare Part B Physician Services Program had two very different antecedents. Medicare Part A was modeled on the Blue Cross hospital insurance plans developed and organized during the Great Depression by the hospitals themselves. Blue Cross only

covered hospital services, together with some hospital-based physicians (e.g., pathologists, radiologists and anesthesiologists) and reimbursed the hospitals, which were almost all non-profits, directly based on their actual costs to provide the services. Importantly, hospitals received different reimbursement for the same services based on their individual cost structure. Medicare Part A copied the Blue Cross reimbursement model and paid hospitals directly based on Medicare's share of a hospital's actual and reasonable costs. Like Blue Cross, each hospital received different amounts of reimbursement depending upon their individual costs and their mix of patients (e.g., Medicare, commercial, self-pay).[2]

35. In contrast, the Part B program was modeled on the very different Blue Shield insurance programs. Blue Shield insurance was developed by physicians and designed to limit insurance company influence over the physician-patient relationship, including pricing. Blue Shield was structured as an indemnity insurance contract directly between the insurer (Blue Shield) and the insured patient; there was no contractual relationship between the insurer and the physician or other health care supplier.[3]

36. The Blue Shield insurance contract required the insurer to reimburse the patient for a percentage of the non-hospital medical costs actually incurred and paid by the patient, subject to a cap based on the usual and customary charges of physicians or suppliers in the area. The costs incurred by the physician or supplier to produce the service were irrelevant because reimbursement was based not on the supplier's actual cost but on the actual price charged to the patient. Medicare Part B adopted the Blue Shield model in part because the AMA was opposed to any program pursuant to which the federal government would directly set physician payment rates or directly pay physicians.[4]

37. The basic indemnity benefits of Medicare Part B are described in SSA § 1833, 42 U.S.C. § 1395(l). With respect to Epogen and Zemplar, Medicare's obligation is:

> *[T]here shall be paid* from the Federal Supplementary Medical Insurance Trust Fund, *in the case of each individual who is covered under the insurance program* established by this part *and incurs expenses for services with respect to which benefits are payable under this part*, amounts equal to:
> (S) with respect to drugs and biologicals … not paid on a cost or prospective payment basis …, the amounts paid shall be *80 percent of the lesser of the actual charge or the payment amount established [elsewhere in the SSA]*

[2] See, Paul Starr, The Social Transformation of American Medicine, Basic Books (1982), pgs. 289-334, 385.
[3] Id.
[4] Id.

Simply stated, Medicare Part B as an indemnity insurance plan will reimburse the *enrollee* (i.e., "the individual who is covered under [Medicare]") for 80% of the enrollee's incurred expenses for drugs or biologics based on the supplier's actual charges subject to a cap. In other words, section 1833 states the overarching principle that Medicare will not reimburse a Medicare enrollee for services that he or she received for free. It does not address the supplier's actual costs but instead addresses its actual charges.

38. These historical and significant differences between Part A cost-based reimbursement and Part B charge-based reimbursement are reflected throughout the Medicare statute and regulations. For example, Medicare Part A was an automatic entitlement program, requires no premium from enrollees, and minimal copayments. Medicare Part B was optional, requires enrollees to pay substantial premiums, and requires enrollees to pay 20% copayments for most services. Original Medicare Part A reimbursed hospitals directly based on their individual actual and reasonable costs, while original Medicare Part B reimbursed enrollees based on the usual and customary charges of their area physicians or suppliers for services the enrollees actually received. Medicare Part A providers can be excluded from the program if they claim "substantially in excess" of their usual costs; Medicare Part B suppliers may be excluded if they charge Medicare enrollees "substantially in excess" of their usual charge to other patients. SSA § 1128(b)(6), 42 U.S.C. § 1320a-7(b)(6). Medicare Part A hospitals are required to be prudent purchasers because they are reimbursed on their costs; Medicare Part B has no comparable requirement for Part B suppliers because their costs are irrelevant. See, e.g., 56 Fed. Reg. 35952, 35979(July 29, 1991)("[W]e believe that this revision is consistent with HCFA's prudent buyer rules, which are not applicable to charge-based health care providers.").

39. While the Medicare Part B program has evolved over time, it continues to be structured as an indemnity program that reimburses enrollees for actual charges enrollees have incurred for non-inpatient services (subject to a cap) and not on the physicians' or suppliers' costs to produce the services. While the cap has changed, the basic payment obligation has not. The original cap based on usual and customary charge in the community now typically takes the form of a fee schedule of some kind. E.g. 42 C.F.R. Part 414 (payment under physician fee schedule); 42 C.F.R. Part 416 (payment under ambulatory surgery center fee schedule). However, the payment obligation is still the "lesser of" the supplier's actual charge or the applicable cap. Similarly, the primary payment obligation under Part B is still to the enrollee and not the supplier. Payments to suppliers are made pursuant to an assignment from the enrollee of his or her right to payment. SSA § 1842(b)(3), 42 U.S.C. § 1395u(b)(3). In the mid-1980s, Medicare encouraged physicians to accept assignment for Medicare claims, thereby allowing physicians to submit claims directly to Medicare and receive payment directly from Medicare. Physicians who refused to accept assignment received lower reimbursement and were still required to submit the claims directly on behalf of Medicare enrollees. In short, the Medicare Part B program makes payments directly to most suppliers only because the

suppliers have accepted the assignment of their patients' right to reimbursement from Medicare.

40. Second, the common understanding that suppliers could bill Medicare for items or services provided to their patients, irrespective of the suppliers' costs to deliver those items or services, was completely consistent with the Medicare statute and regulations. The statutory exclusions from Medicare Part A and B are set out in section 1862 of the Social Security Act. There is no exclusion of coverage for Part B items or services based on the costs to a physician or supplier in the provision. Rather, §1862 (a)(2) provides:

> [N]o payment may be made under … part B for any expenses incurred for items or services … for which the individual furnished such items or services has no legal obligation to pay, and which no other person … has a legal obligation to provide or pay for, except in the case of Federally qualified health center.

As discussed in ¶33, §1862(a)(2) simply restates the basic principle of indemnity insurance: the insurer is not liable to the policyholder unless the policyholder actually incurs an expense (i.e., a loss).

41. This exclusion is completely consistent with the overall structure of Medicare Part B as an indemnity contract between Medicare and the enrollee, by providing that Part B will only pay for items or services for which the enrollee has actually incurred expenses or has an obligation to pay. Both the industry and CMS have shared that understanding of the provision. See, Medicare Benefits Coverage Manual, Chap. 16, § 40 [5]; CMS Medicare Learning Network, Items and Services Not Covered Under Medicare.[6] Similarly, CMS' reference to §1862(a)(2) as authority for Medicare Claims Processing Manual Chapter 32, § 67 on no-cost claims would have been understood to apply to no cost items for which the enrollee had no obligation to pay either by statute (e.g., drug samples which the Prescription Drug Marketing Act prohibited physicians from reselling) or by contract (e.g., device manufacturers that provided a sample or demonstration device pursuant to an agreement not to bill or charge patients or clinical trials).

42. Third, the common understanding that physicians and suppliers could bill Part B for covered items and services provided to enrollees, regardless of the costs incurred by the physician or supplier in providing the items or services was consistent with the overall rationale and structure of the Part B insurance program. Because payment was based on the lesser of a supplier's actual charges or the fee schedule, why would a supplier be prohibited from billing for an item if he or she

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[5] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c16.pdf

[6] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Items_and_Services_Not_Covered_Under_Medicare_BookletICN906765.pdf

received it for free, but permitted to bill for it if the supplier had paid $ .01 for the same item? In either case, the enrollee would have received the same service, the charge by the supplier would be the same, and Medicare would be paying for the service provided at the lower of the charge or the fee schedule. How would a supplier bill for a service for which he or she incurred no costs for some but not all the inputs necessary to produce the service? Both regulators and the industry understood that tying payment to a supplier's costs was inconsistent with the rationale and structure of the Part B insurance program, unworkable in operation, and unfair to the supplier.

43. Fourth, the industry understanding of the difference between Part B charge-based reimbursement and Part A cost-based reimbursement was consistent with Medicare fraud and abuse enforcement guidance. For example, the differences between Part A and Part B programs were reflected in the OIG's AKS safe harbor discount regulation. 42 C.F.R. §1001.952(h). In order for a seller's discount, which would include the provision of an item at no cost, to a Part B supplier to qualify for a safe harbor, the OIG initially proposed that that the physician or supplier would be required to reduce its charge to Medicare by the amount of the reduction. 54 Fed. Reg. 3088, 3093 (January 23, 1989). In other words, if the supplier had received the item for free, it could not bill the Medicare Part B program. The final 1991 rule, however, eliminated the requirement that the Part B charge be reduced by the amount of the discount and only required that the amount of the discount be disclosed. Some commenters complained that cost-based providers were being treated differently from charge-based suppliers. The OIG responded:

> [W]e note that some commenters were confused about the requirements we are placing on health care providers reimbursed on the basis of costs. The regulation need not specify that a [cost-based] health care provider must separately reduce its cost by the amount of the discount because the cost reporting requirements accomplish the statutory purpose of having the amount of the discount "appropriately reflected in the costs claimed." ... As a result, this revised discount provision treats items and services reimbursed on the basis of charges differently from those reimbursed on the basis of costs, because costs will be reduced by the amounts of discounts whereas charges will not be affected.

56 Fed. Reg. 35952, 35980 (July 29, 1991). In other words, the OIG recognized that Medicare Part B payment was unrelated to the supplier's costs and that suppliers could submit and receive Part B payment, regardless of their actual costs for the items or services.

44. Importantly, the industry understood that as a matter of course the OIG regulations would have been reviewed and approved by the Health Care Financing Administration, the predecessor to CMS. If HCFA understood that charge-based suppliers were prohibited from billing Medicare Part B unless they had incurred a

cost for the item, it would not have approved the final regulation, which merely required reporting the discounted amount.

45. Similarly, the OIG modified the discount safe harbor in 1999 to specifically permit sellers, such as a drug manufacturer, to offer a good for free or at a reduced price so long as the purchaser bought another good that was reimbursed using the same methodology. Both the regulators and the industry understood that the "free" goods would be used in the provision of health care services and included in services charged to Medicare. In fact, unless the purchaser could bill Medicare for the free good, the free good would have no value to the supplier and would not have implicated the anti-kickback statute at all.

46. At all times while I was at the OIG, it was my understanding that suppliers were permitted to bill Medicare Part B for items and services regardless of the cost, if any, of the items to the supplier, unless there was a specific prohibition, such as for drug samples.[7] In the regular course of my duties, industry participants would ask whether a supplier that was billing Medicare for some item that it obtained at no or extremely low cost was in violation of the law. I would explain to them the difference between Medicare's cost-based and charge-based reimbursement methodology and that, under the latter methodology, a supplier's costs were irrelevant. My understanding of the law was consistent with the general understanding in the industry and among health care regulators.

47. Finally, the issue of whether it was proper to bill Medicare Part B for free goods is distinct from the question of whether a supplier can bill for pharmaceutical "samples." Drug samples are a very defined category of drugs with specific labeling and distribution rules. (Overfill is not a drug sample.) The Prescription Drug Marketing Act ("PDMA") was enacted in 1988 and expressly prohibited the physicians from selling (or billing) anyone for the samples. PDMA, not Medicare rules or regulations, prohibited the sale of free sample pharmaceuticals until 2007 when CMS issued sub-regulatory guidance that Part B suppliers could not bill for free samples received from manufacturers.[8]

48. CMS' prohibition on billing for pharmaceutical "samples" as well as its prohibition on billing for goods provided for free for use in clinical studies were understood to be exceptions to the general rule that a supplier's costs were irrelevant to charge based reimbursement. By specifically excluding reimbursement for only certain goods received for free by suppliers, CMS appeared to confirm that other free goods could be provided to enrollees and billed to the Medicare program.

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[7] I maintained this view after my departure from OIG. See Doc. 105-1 (September 28, 2006 BNA Health Care Daily Report article with my explanation that it is a "myth" that entities cannot bill Medicare for any goods they received for free).

[8] http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1147Cp.pdf (showing section 67 as new, issued January 5, 2007).

49. In my work on this case, I have reviewed the materials related to the Hamel False Claims Act case. See Fresenius-CS-49237-43; 082705; 052372; 52465. That case alleged that a predecessor company to Fresenius violated the FCA by billing for drugs used in a clinical trial and in billing for overfill. Consistent with the distinction I make above, the government dismissed the overfill allegations without taking any action and Fresenius settled only the clinical trial matter. This is consistent with well-understood differences between the rules governing clinical trials and those involving overfill. When the government wishes to bar billing for "free" or certain kinds of goods, it does so clearly.

50. The logical conclusion, consistent with the structure and history of Part B, the statutory and regulatory language, and the common understanding in the industry, was that billing for overfill was lawful, and Fresenius thus reasonably believed that it could do so.

VI. Statement of and Bases for Opinion No. 3

51. It was reasonable for Fresenius to believe it was appropriate to bill Medicare for overfill. As set out above, the consensus in the health care bar, in the industry and among regulators was that overfill was part and parcel of the vial that was purchased. Even assuming that overfill was free, which few would have assumed, it was reasonable for Fresenius to believe it could bill Medicare for overfill.

52. In addition to the reasons set forth in the prior two sections, the conclusion that Fresenius could bill Medicare for overfill was consistent with agency enforcement actions, or more accurately, the absence of enforcement actions, despite the open and widespread use of pharmaceutical overfill throughout the industry which was well known to both CMS and OIG. See Ex. 4; ¶¶ 30-31, supra. This was true both before and after the adoption of the ASP methodology.

53. Several divisions of the OIG were aware of dialysis company billing for overfill, and OIG was aware of this practice occurring before, during, and after the implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") and the ASP payment methodology. Ex. 4 see also Caucci Dep., pp. 75, 147 (describing her understanding that Fresenius was billing for overfill through the 2008 expiration of the Corporate Integrity Agreement); Tawes Dep., pp. 80-81. As part of my work in this case, I reviewed the depositions of Nicole Caucci and David Tawes. Both of these individuals were employees of OIG who are knowledgeable about the rules governing ESRD facilities. In my experience, OIG would have taken action if it concluded that conduct reported to it violated any rules. Ms. Caucci testified she: (1) never concluded that the use of and billing for overfill was a breach of Fresenius' Corporate Integrity Agreement; (2) never sent Fresenius any corrective action plan related to its overfill use; (3) never imposed any sanctions on Fresenius based on overfill; and (4) never believed at any point during the Corporate Integrity Agreement that CMS had a policy prohibiting the use or billing of overfill. Caucci Dep. pp. 21-23, 124; see also 62 Fed. Reg. 55812 (Oct. 28, 1997); 69 Fed. Reg. 40388 (July 2, 2004). Mr. Tawes, who was also aware

of Fresenius' overfill use and billing, testified that if he identified suspected fraud, he would report it. Tawes Dep., p. 10.

54. Likewise, CMS was aware of the overfill practices of dialysis companies. E.g., Caucci Dep. Ex. 29 (emails between OIG and CMS regarding overfill); Hartstein Dep., p. 22 (describing his awareness of overfill billing in 2009). I have reviewed the deposition of CMS' designated witness on this matter, Marc Hartstein. Mr. Hartstein confirmed that the adoption of the ASP methodology did not affect the rules governing overfill billing in any way. Hartstein Dep., p. 49 (testifying that the adoption of the ASP methodology did not "change CMS's policies about which units were reimbursable" and did not "affect the rules governing overfill billing in any way"). As Mr. Hartstein further acknowledged, there was nothing "about the rules that govern overfill that was changed by virtue of the Medicare Modernization Act or the movement to ASP pricing." Hartstein Dep., p. 127-128. As Mr. Hartstein testified, CMS would not pay claims if a practice violated any regulations or statues.

55. The DOJ was likewise informed of overfill practices. E.g. Caucci Dep. Ex. 18 (DOJ Whitepaper submitted by Gambro); Ex. 4 hereto (describing contacts between Fresenius and DOJ).

56. If billing for overfill was unlawful, the government would have taken steps to end it. The reasonable conclusion was that the government's lack of concern with the industry's billing for overfill was based on the government's understanding that such billing was appropriate and lawful either because overfill was purchased product or because billing for free product was appropriate.

VII. Statement of and Bases for Opinion No. 4

57. Fresenius would have reasonably understood that it would have been illegal for Fresenius to provide Epogen and Zemplar overfill to Medicare enrollees without charging them.

58. The relator suggests that, although the government knew that Fresenius and other facilities were using the overfill in treating patients, the government did not know that the facilities were billing Medicare for the drugs. That is not the case. I was in the OIG at the time and knew that dialysis and other health care entities routinely administered and billed Medicare for overfill. Based on my experience, that knowledge was widely shared in OIG, CMS, and DOJ. In any event, Ex. 4 and the deposition testimony of the witnesses establish beyond question that all relevant agencies were aware of these matters. By way of example, Fresenius disclosed that overfill improved its "profit margin" (OIG-008051) and that "we are currently able to utilize Zemplar overfill and bill the actual dose administered" (OIG-003411). Ms. Caucci testified that Fresenius disclosed it was using and billing for overfill. Caucci Dep., p. 31.

59. Moreover, the relator's apparent hypothesis that the government knew that Fresenius was administering overfill but thought that Fresenius was not billing for it ignores the fact that such conduct would have been considered illegal by regulators.

60. The provision of Epogen and Zemplar to Medicare enrollees without charge would have violated the civil money penalty law ("CMP") provision that prohibits persons from offering or giving remuneration to a Medicare or Medicaid enrollee that is likely to influence their selection of a health care provider or supplier. 42 U.S.C. § 1320a-7a(5). The practice would also implicate and potentially violate the federal health program anti-kickback statute and the civil false claims act.

61. The OIG has a longstanding concern with Medicare and Medicaid providers and suppliers giving federal health care program enrollees anything of value, including services without charge, that might influence the enrollees' selection of a health care provider or supplier. The concern is that the remuneration is an inducement to the enrollees to self-refer to the provider or supplier. The provision of overfill, without requiring any copayment, on an ongoing basis would violate the CMP and potentially risk exclusion from the federal health care programs.

62. CMS's designated witness in this case confirmed in his deposition that all drugs administered to patients should be billed to Medicare and that CMS had rules against giving drugs to patients without charge due to it being an inducement to the patient. Hartstein Dep., p. 37-39.

63. The provision of Epogen and Zemplar overfill without charge to dialysis patients would have substantial value to the patients because it would avoid costs that the patients would otherwise have to incur. Generally, Medicare requires that enrollees receiving injectable drugs under Part B must pay 20% of the Medicare allowable charge. For patients with chronic conditions such as dialysis patients, the copayment costs can be very substantial over time. If a facility provided the overfill without charge, the patient receiving the free drugs would avoid the cost of the otherwise applicable copayments for the drugs. The cost savings to a dialysis patient would significantly exceed the OIG's *de minimis* benefit limit for purposes of the CMP statute of $50 per year, particularly in the case of Epogen.

64. The benefit is likely to induce patients to receive treatment from ESRD suppliers that give the free drugs. The OIG has repeatedly stated that providing free or valuable services to current patients constitutes an inducement to select the supplier for future services. In the cases of ESRD patients, there are multiple suppliers and a long term need for services. Indeed, the government witnesses in this case have recognized these principles in their testimony. Caucci Dep., p. 26-27.

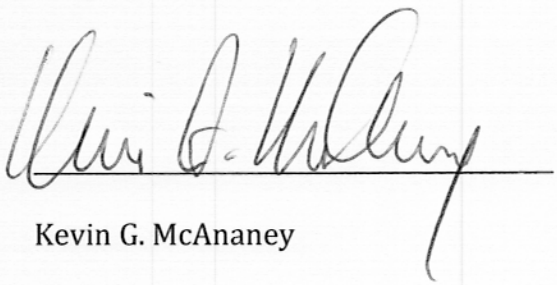
65. The provision of these drugs without charge would also implicate criminal penalties under the AKS. The statute prohibits the knowing and willful offer, payment, solicitation, or receipt of anything of value to induce the referral of federal health care program patients or business. The OIG has long interpreted the AKS to apply to any inducements offered to patients to self-refer. In light of the prohibition in the CMP, any supplier that offered free drugs to Medicare patients would almost certainly possess the requisite knowledge that the activity was unlawful that would trigger AKS liability.

66. These provisions and the OIG's position on inducements to beneficiaries were well known and understood by the health care industry. The repeated

discussions in the OIG's advisory opinions and the 2002 Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries[9] received broad dissemination in health care publications and other communications.

Conclusion

For the reasons set out above, it is my opinion that throughout the relevant time period, experienced counsel, regulators, and industry leaders reasonably believed that renal dialysis facilities were permitted to bill and receive payment from Medicare for Epogen and Zemplar overfill. Having paid for the contents of the vial, providers were permitted to bill Medicare. Whether the overfill was considered part of the purchase price or an extra quantity was irrelevant. If the provider owned the product and administered it to a Medicare patient, the provider was entitled to charge Medicare and receive payment. Fresenius at all times relevant shared that understanding, acted upon that understanding, informed the regulatory community of its understanding, and received no guidance from the regulatory community to the contrary.



Kevin G. McAnaney

11/26/14

Date

[9] http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf